

Exhibit 1
Defendants' Invalidity Contentions,
May 3, 2024
(Excerpted)

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

		X
		:
ASTRAZENECA PHARMACEUTICALS LP,		:
ASTRAZENECA UK LIMITED, KUDOS		:
PHARMACEUTICALS LIMITED, THE		:
UNIVERSITY OF SHEFFIELD, and MSD		:
INTERNATIONAL BUSINESS GMBH,		:
		:
Plaintiffs,		:
		:
v.		:
		:
NATCO PHARMA LIMITED and NATCO		:
PHARMA INC.,		:
		:
Defendants.		:

	:	x
	:	
ASTRAZENECA PHARMACEUTICALS LP,	:	Honorable Robert Kirsch, U.S.D.J.
ASTRAZENECA UK LIMITED, KUDOS	:	
PHARMACEUTICALS LIMITED, THE	:	
UNIVERSITY OF SHEFFIELD, and MSD	:	Civil Action No. 24 CV 641 (RK)(TJB)
INTERNATIONAL BUSINESS GMBH,	:	(Consolidated)
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
SANDOZ, INC.,	:	
	:	
Defendant.	:	

DEFENDANTS' INVALIDITY CONTENTIONS

this analysis are compared “based on the expiration date of the patent after PTA has been added.” *In re: Collect*, 81 F.4th at 1229. The expiration date of the 530 patent is July 23, 2024. The expiration date of the 701 patent is September 24, 2024, which includes 62 days of PTA. Per the Orange Book, the claim of the 562 patent expires on August 4, 2031, which includes 2,568 days of patent term adjustment.¹³ (*See also* PTO Patent Center). Because the expiration date of the 562 patent is after the expiration date of the 701 patent and the 530 patent, the claim of the 562 patent is the later-expiring claim in a non-statutory double patenting analysis, and the claims of both the 701 patent and 530 patent are thus earlier expiring.

Second, the 562 patent and both the 701 patent and 530 patent share a common inventor, Thomas Helleday. Thus, an obviousness-type double patenting analysis is appropriate, even though the 562 patent issued from a different application than did the 701 patent and, in part, the 530 patent. *Otsuka Pharm. Co. v. Sandoz, Inc.*, 2010 WL 11636594, at *6 (D.N.J. Dec. 15, 2010), *aff’d*, 678 F.3d 1280 (Fed. Cir. 2012) (citing *Sun Pharm.*, 611 F.3d at 1389); *see also In re Hubbell*, 709 F.3d 1140, 1146-47 (Fed. Cir. 2013) (in the context of an application and a patent that had two common joint inventors, but different inventive entities and no common owners or assignees, the court held that complete identity of ownership or inventive entities is not a prerequisite to a non-statutory double patenting rejection). This conclusion is warranted by and consistent with at least MPEP 804, and Exhibit A. Defendants incorporate by reference, as if set forth fully herein, the file history of the 562 patent and all bases the Examiner and/or the PTAB recited for assessing the 701 and 530 patents as double patenting references.

¹³ To the extent Plaintiff argues that any patent term adjustment should not be considered on the basis that it was granted due to PTO delays that were not the fault of the patentee, such arguments are not only incorrect, as discussed further below, but are also irrelevant. *In re: Collect*, 81 F.4th 1230 (“The ability of the applicant to show good faith during prosecution does not entitle it to a patent term to which it otherwise is not entitled.”).